

## REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-2, 4-7, 10-12, 14-26 and 28-30 are pending. The claim amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. For example, the limitations previously recited in claims 8 and 9 are incorporated into the independent claims. Non-elected claims 25-30 were withdrawn from consideration by the Examiner. Their rejoinder is requested upon allowance of an elected claim.

### *Information Disclosure Statement*

To satisfy their continuing duties of candor and good faith, Applicants bring to the attention of the Examiner related subject matter in Serial Nos. 10/849,544, 11/543,991, 12/088,080 and 12,443,804. He is invited to consider their prosecution histories and the prior art of record in those applications, which are accessible through the PTO's Image File Wrapper (IFW), in view of the Federal Circuit's holding in *McKesson Information Solutions v. Bridge Medical*, 82 USPQ2d 1865 (Fed. Cir. 2007). To avoid duplication of those materials in the PTO's records, reference to the IFW is encouraged but Applicants would submit copies of these materials for the Examiner's review if he prefers.

Three foreign patent documents were not considered by the Examiner. They are being resubmitted for consideration. Their consideration is appropriate because English counterparts to the foreign language disclosures are attached.

### *Statement of the Substance of the Interview*

The undersigned acknowledges the courtesy of the Examiner and his supervisor during the interview on February 22, 2010. Proposed claim amendments and the documents cited in the Section 103 rejections were discussed, but there was no agreement on allowable subject matter. The foregoing is Applicants' statement of the substance of the interview. But if anything else is required to complete the record, do not hesitate to contact the undersigned.

35 U.S.C. 103 – Nonobviousness

A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d 1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See *id.* (“Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue”). The use of hindsight reasoning is impermissible. See *id.* at 1397 (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning”). Thus, a *prima facie* case under Section 103(a) requires “some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct.” *Kahn* at 1335; see *KSR* at 1396. An inquiry is required as to “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 1396. But a claim that is directed to a combination of prior art elements “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* Finally, a determination of *prima facie* obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Claims 1-2, 4-12 and 14-21 were rejected under Section 103(a) as allegedly unpatentable over AOKI et al. (WO 03/43661) in view of NAKAJIMA (JP 2000-128779). Applicants traverse because the amount of hydrophobic wax in the claimed composition is critical to the invention’s characteristic, which was not expected from the prior art.

Declaration evidence comparing Applicants’ claimed invention to the closest prior art will be submitted to show the criticality of the range from 20 to 35 wt%, based on the weight of the release-controlling coating, of a hydrophobic wax (e.g., magnesium stearate). As a result of these studies on the relationship between the composition’s ratio of

hydrophobic wax in the release-controlling coating and the pulsatile dissolution property of the composition, it was confirmed that the claimed range is critical. Where the ratio is lower than this range, the dispersed components aggregated in the coating suspension, whereby the variation in the dissolution lag time increased. Moreover, where the ratio was higher than this range, the strength of the release-controlling coating decreased, whereby the acid resistance could not be ensured and a suitable dissolution lag time could not be obtained.

Neither AOKI nor NAKAJIMA predicts this dissolution property of a composition with a reasonable expectation of success. Therefore, claims 1-2, 4-12 and 14-21 would not have been obvious to one of ordinary skill in the art. Since this feature of Applicants' claimed invention is sufficient to distinguish over the cited documents, other incorrect allegations about their disclosures are not disputed here. But the opportunity to dispute them in the future is reserved.

Claims 22-24 were rejected under Section 103(a) as allegedly unpatentable over AOKI in view of NAKAJIMA as applied above, and further in view of WHITTLE (US 6,444,689). Applicants traverse for the reason explained above.

The failure of AOKI and NAKAJIMA to disclose the claimed invention is not remedied by the attempt to combine their disclosures with WHITTLE. None of the cited documents predicts the unexpected dissolution property of Applicants' claimed composition with a reasonable expectation of success. Therefore, claims 22-24 would not have been obvious to one of ordinary skill in the art. Since this feature of Applicants' claimed invention is sufficient to distinguish over the cited documents, other incorrect allegations about their disclosures are not disputed here. But the opportunity to dispute them in the future is reserved.

Claims 1-2, 4-12 and 14-21 were rejected under Section 103(a) as allegedly unpatentable over SAEKI et al. (US 5,035,899) in view of AOKI et al. (WO 03/43661). Applicants traverse because the amount of hydrophobic wax in the claimed composition is critical to the invention's characteristic, which was not expected from the prior art.

Declaration evidence comparing Applicants' claimed invention to the closest prior art will be submitted to show the criticality of the range from 20 to 35 wt%, based on the

weight of the release-controlling coating, of a hydrophobic wax (e.g., magnesium stearate). As a result of these studies on the relationship between the composition's ratio of hydrophobic wax in the release-controlling coating and the pulsatile dissolution property of the composition, it was confirmed that the claimed range is critical. Where the ratio is lower than this range, the dispersed components aggregated in the coating suspension, whereby the variation in the dissolution lag time increased. Moreover, where the ratio was higher than this range, the strength of the release-controlling coating decreased, whereby the acid resistance could not be ensured and a suitable dissolution lag time could not be obtained.

Neither SAEKI nor AOKI predicts this dissolution property of a composition with a reasonable expectation of success. Therefore, claims 1-2, 4-12 and 14-21 would not have been obvious to one of ordinary skill in the art. Since this feature of Applicants' claimed invention is sufficient to distinguish over the cited documents, other incorrect allegations about their disclosures are not disputed here. But the opportunity to dispute them in the future is reserved.

Claims 22-24 were rejected under Section 103(a) as allegedly unpatentable over AOKI in view of NAKAJIMA as applied above, and further in view of CHEN et al. (US 2002/ 0045184). Applicants traverse for the reason explained above.

The failure of AOKI and NAKAJIMA to disclose the claimed invention is not remedied by the attempt to combine their disclosures with CHEN. None of the cited documents predicts the unexpected dissolution property of Applicants' claimed composition with a reasonable expectation of success. Therefore, claims 22-24 would not have been obvious to one of ordinary skill in the art. Since this feature of Applicants' claimed invention is sufficient to distinguish over the cited documents, other incorrect allegations about their disclosures are not disputed here. But the opportunity to dispute them in the future is reserved.

Withdrawal of the Section 103 rejections is requested because the claims would not have been obvious to one of ordinary skill in the art when this invention was made.

*Double Patenting*

Claims 1-2, 4-12 and 14-20 were provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-3, 7 and 10-12 of copending Application No. 10/849,544 in view of AOKI and NAKAJIMA. It was also alleged that claims 1-3, 7 and 10-12 are directed to an invention not patentably distinct from claims 1-3, 5-8 and 10-12 of commonly assigned Application No. 10/849,544. Applicants traverse for the reason explained above.

Claims 1-2, 4-12 and 14-20 were provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 41-43 and 45-55 of copending Application No. 10/938,554 in view of AOKI and NAKAJIMA. It was also alleged that claims 41-43 and 45-55 are directed to an invention not patentably distinct from claims 41-43 and 45-55 of commonly assigned Application No. 10/938,554. Applicants traverse for the reason explained above.

Withdrawal of the double patenting rejections is requested because the amount of hydrophobic wax in the claimed composition is critical to the unexpected dissolution property of Applicants' claimed composition.

*Conclusion*

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if additional information is required.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

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